

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Ts'o et al.

Application No. 09/888,164

Filed: June 22, 2001

LIGANDS TO ENHANCE CELLULAR For:

UPTAKE OF BIOMOLECULES

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Washington, D.C. 20231

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the of each of the references. complete record and is not a concession that the right is expressly reserved to establish an invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to represents art that is relevant of analogous to the claimed involution. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

within any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action 図 after the filing of a request for continued examination under 37 CFR 1.114.

In re Appln. of Ts'o et al. Application No. 09/888,164 after (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes one of: the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below). or П the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below). after the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application. and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below). after the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and within thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below). NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed. Copies of the References \boxtimes Copies of the references listed on the enclosed Form 1449 are enclosed herewith. Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).

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A copy of the foreign search report is enclosed herewith.
The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

	U.S. APPLICATIONS	St	atus (check o	ne)		
学。U.	S. APPLICATIONS U.S. FILING DATE	PATENTED	PENDING	ABANDONED		
1.						
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Stater	ment under 37 CFR 1.97(e)					
	The undersigned hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.					
	The undersigned hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.					
Stater	ment under 37 CFR 1.704(d)					
	The undersigned hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.					
Fees						
	No fee is owed by the applicant(s). The IDS Fee of \$180 under 37 CFR 1.17(p)	is enclosed he	erewith.	-		
Metho	od of Payment of Fees					
	Attached is a check in the amount of \$ Charge Deposit Account No. 12-1216 in the this communication is enclosed for that purposed.		. (A du	plicate copy of		
Autho	orization to Charge Additional Fees					
	If any additional fees are owed in connection Deposit Account No. 12-1216. (A duplicate for that purpose.)					

In re Appln. of Ts'o et al. Application No. 09/888,164

Instructions as to Overpayment

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Date: January 28, 2002

CERTIFICATE OF MAILING

I hereby certify that this INFORMATION DISCLOSURE STATEMENT (along with any documents referred to as being attached or enclosed) is being deposited with the United States Postal Service via Fist Class Mail to Addressee in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231

Date: 01-28-02

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				First Named Inventor	Ts'o et al.
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(Use as many sheets as necessary)				Examiner Name	·
Sheet	1	of	6	Attorney Docket Number	212241

				U.S. PATENT DOCUMENTS		
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Examiner Initials	Doc. No.	Application or Patent Number	Kind Code	Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

First Named Inventor **Group Art Unit** Examiner Name

09/888,164

Ts'o et al.

June 22, 2001

(Use as many sheets as necessary)

Attorney Docket Number 212241 Of U.S. PATENT DOCUMENTS

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		OTHER - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, line) article (authors) and authors (in CAPITAL LETTERS), title of the article (when appropriate), publisher, city	Trans	lation No
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COMECH CENTER 1600/2900 Substitute for form 1449A/B/PTO Application Number 09/888,164 Filing Date June 22, 2001 INFORMATION DISCLOSURE First Named Inventor Ts'o et al. STATEMENT BY APPLICANT Group Art Unit **Examiner Name** (Use as many sheets as necessary) Sheet Attorney Docket Number 212241 of OTHER - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, Translation Examiner Doc. magazine, journat, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city-Initials Yes Nο and/or country where published. AGRIS et al., "Inhibition of Vesicular Stomatitis Virus Protein Synthesis and Infection by CZSequence-Specific Oligodeoxyribonucleoside Methylphosphonates," Biochemistry, 25: 6268-6275 (1986). AKHTAR et al., "Stability of Antisense DNA Oligodeoxynucleotide Analogs in Cellular X Extracts and Sera," Life Science, 49: 1793-1801, (1991). ALT et al., "Core Specific Antisense Phosphorothioate Oligodeoxynucleotides as Potent DΒ and Specific Inhibitors of Hepatitis C Viral Translation," Arch. Virol, 142: 589-599 (1997). ANDERSSON, "Reduction and Reoxidation of the Disulfide Bonds of Bovine Serum DC Albumin," Archives of Biochemistry and Biophysics," 133: 277-285 (1969). ASAYAMA et al., "Synthesis Of Novel Polyampholyte Comb-Type Copolymers Consisting DD Of A Poly (L-Lysine) Backbone And Hyaluronic Acid Side Changes For A DNA Carrier, " Bioconjugate Chem., 9: 476-481 (1998). BIDER et al., "Ligand-induced Endocytosis of the Asialoglycoprotein Receptor: Evidence DΕ Ø for Heterogeneity in Subunit Oligomerization," FEBS Lett. 434: 37-41 (1998). BIESSEN et al., "Cholesterol Derivative of a New Triantenarry Cluster Galactoside Directs DF Low- and High-density Lipoproteins to the Parenchymal Liver Cell," Biochem. J., 302: 283-289 (1994). BIESSEN et al., "Synthesis of Cluster Galactosides with High Affinity for the Hepatic DG Asialoglycoprotein Receptor," J. Med. Chem., 38: 1538-1546 (1995). DН BIESSEN et al., "Cholesterol Derivative of a New Triantenarry Cluster Galactoside Lowers Serum Cholesterol Levels and Enhances Secretion of Bile Acids in the Rat," Circulation, 91: 1847-1854 (1995). BIESSEN et al., "Targeted Delivery of Oligonucleotides to Parenchymal Liver Cells in DI Vivo," Biochem. J., 340: 783-792 (1999). BIESSEN et al., "Targeted Delivery of Antisense Oligonucleotides to Parenchymal Liver DJ B Cells in Vivo, "Methods in Enzymology, 314: 324-342 (1999). BIESSEN et al., "Novel Hepatotrophic Prodrugs of the Antiviral Nucleoside 9-(2-DK Phosphonylmethoxyethyl) Adenine with Improved Pharmacokinetics and Antiviral Activity," FASEB J., 14: 1784-1792 (Sept. 2000). BONFILS et al., "Drug targeting: Synthesis and Endocytosis of Oligonucleotide-DL 1 Neoglycoprotein Conjugates," Nucleic Acids Res., 20(17): 4621-4629 (1992). BOUSSIF et al., "A Versatile Vector for Gene and Oligonucleotide Transfer into Cells in DM Culture and in Vivo: Polyethylenimine," Proc. Natl. Acad. Sci. USA, 92: 7297-7301 (1995). DN BRETON et al., "Production of Macrophage-derived Cytotoxic Factor by N-[3-[(Carbamoylmethyl)thio]propionylated] Neoglycoproteins," Bioconjugate Chemistry, 2: 16-18 (1991). BRUIX, "Treatment of Hepatocellular Carcinoma," Hepatology, 25: 259-262 (1997). DO BUNNELL et al., "Targeted Delivery of Antisense Oligonucleotides by Molecular Þ Conjugates," Somatic Cell and Molecular Genetics, 18(6): 559-569 (1992). CARUTHERS, "Chemical Synthesis of DNA and DNA Analogues," Acc. Chem. Res. 24: DQ P 278-284 (1991). CATTANEO-PANGRAZZI et al., "Cell-cycle Arrest and p53-independent Induction of DR Apoptosis in Vitro by the New Anticancer Drugs 5-FdUrd-P-FdCydOct and dCydPam-P-FdUrd in DU-145 Human Prostate Cancer Cells," J. Cancer Res. Clin. Oncol., 126: 247-256 (May 2000). CHENG et al., "Characterization of an Antineoplastic Glucuronide Prodrug," Biochem. DS Pharmacol., 58: 325-328 (1999). CHIPOWSKY et al., "Synthesis of 1-thioaldosides Having an Amino Group at the Aclycon DT Terminal," Carbohydrate Res., 31: 339-346 (1973).

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Initials	No.	magazine, journal, serial, symposium, catalog	g, etc.), date, page(s), volum country where published.	ne-issue number (s), publisher, city	Yes	No
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INFORMATION DISCLOSURE

Complete if Known 09/888,164 Application Number June 22, 2001 Filing Date Ts'o et al. First Named Inventor Group Art Unit Examiner Name

STATEMENT BY APPLICANT Attorney Docket Number 212241 (Use as many sheets as necessary) OTHER - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, Translation eque name or the author (in CAPTIAL LETTERS), title of the article (when appropriate), title of the item (bool magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published. Sheet No Yes LEE et al., "Ligand Structural Requirements for Recognition and Binding by the Hepatic Doc. Examiner No. Initials Asialoglycoprotein Receptor," Targeted Diagn. Ther., 4: 65-86 (1991). LEE, "Biochemistry of Carbohydrate-Protein Interaction," FASEB J., 6: 3193-3200 (1992). LEE et al., "Facile Synthesis of a High-Affinity Ligand for Mammalian Hepatic Lectin C Containing Three Terminal N-Acetylgalactosamine Residues," Bioconjug. Chem., 8(5): FΟ FP LEE-YOUNG et al., "Neocglycoconjugates: Preparation and Application," Acad. Press, * LEVIS et al., "Cellular Uptake of Oligodeoxyribonucleoside Methylphosphonates," FQ Inc., 511-537 (1994). p Antisense Research and Development, 5: 251-259 (1995). LU et al., "Antisense DNA Delivery in Vivo: Liver Targeting by Receptor-Mediated Uptake," J. Nucl. Med., 35: 269-275 (1994). MARSHALL et al., "Inhibition of Human Immunodeficiency Virus Activity by Phosphorodithioate Oligodeoxycytidine," Proc. Natl. Acad. Sci. USA, 89: 6265-6269 FT MARTINEZ-FONG et al., "Nonenzymatic Glycosylation of Poly-L-lysine: A New Tool for 7 Targeted Gene Delivery," Hepatology, 20(6): 1602-1608 (1994). MERWIN et al., "Targeted Delivery of DNA using YEE(GalNAcAH)₃, A Synthetic FU Glycopeptide Ligand for the Asialoglycoprotein Receptor," Bioconjugate Chem. 5: 612-MIER et al., "Preparation and Evaluation of Tumor-Targeting Peptide-Oligonucleotide þ Conjugates," Bioconjugate Chem., 11: 855-860 (Nov. - Dec. 2000). MILLIGAN et al., "Current Concepts in Antisense Drug Design," Journal of Medicinal . FW 4 O'CONNOR et al., "Biological Activity of a Novel Rationally Designed Lipophilic Chemistry, 36(14): 1923-1937 (1993). FΧ Thymidylate Synthase Inhibitor," Cancer Chemother. Pharmacol., 34: 225-229 (1994). P OZAKI et al., "The Differences in Structural Specificity for Recognition and Binding FΥ Between Asialoglycoprotein Receptors of Liver and Macrophages," Glycoconjugate FΖ PÉRIGAUD et al., "Nucleoside Analogues as Chemotherapeutic Agents: A Review," + Nucleosides and Nucleotides, 11(2-4): 903-945 (1992). PLANK et al., "Gene Transfer into Hepatocytes Using Asialoglycoprotein Receptor GΑ Mediate Endocytosis of DNA Complexed with an Artificial Tetra-Antennary Galactose GΒ Ligand," Bioconjugate Chem., 3: 533-539 (1992). RANADE, "Drug Delivery Systems: 3A. Role of Polymers in Drug Delivery," J. Clin. ۴ RICE et al., "Defined Geometry of Binding between Triantennary Glycopeptide and the Asialoglycoprotein DNA of Rat Heptocytes," J. Biol. Chem., 265(30): 18429-18434 (1990). 4 RICE et al., "Interterminal Distance and Flexibility of a Triantennary Glycopeptide as Measured by Resonance Energy Transfer," Biochem., 30: 6646-6655 (1991). ۴ RICHARDSON et al., "Potential of Low Molecular Mass Chitosan as a DNA Delivery GE System: Biocompatibility, Body Distribution and Ability to Complex and Protect DNA," Intl. GF ROBINSON et al., "Bioadhesive Polymers for Controlled Drug Delivery," Annals New York 4 ROHLFF et al., "A Novel, Orally Administered Nucleoside Analogu, OGT 719, Inhibits GG the Liver Invasive Growth of a Human Colorectal Tumor, C170HM2," Cancer Res., 59: GΗ 1268-1272 (1999).

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Compl te if Known Substitute for form 1449A/B/PTO Application Number 09/888,164 June 22, 2001 Filing Date INFORMATION DISCLOSURE First Named Inventor Ts'o et al. STATEMENT BY APPLICANT **Group Art Unit Examiner Name** (Use as many sheets as necessary) Sheet Attorney Docket Number | 212241 of OTHER - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item Translation Examiner Doc. (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, Initials Yes No city and/or country where published. GI SCHWARZ et al., "Preparation, Antibacterial Effects and Enzymatic Degradation of 5-Fluorouracil Nucleosides," Collection Czechoslov. Chem. Commun., 45: 3217-3230 SETT et al., "Macrophage-Directed Delivery of Doxorubicin Conjugated to GJ Neoglyoprotein Using Leishmaniasis as the Model Disease," J. Infectious Diseases, 168: 994-999 (1993) SHAW et al., "Modified Deoxyoligonucleotides Stable to Exonuclease Degradation in GK ۴ Serum," Nuc. Acids Res., 19(4): 747-750 (1991). SMITH, "Amphipathic Enzyme-Polymer Conjugates," Nature, 262: 519-520 (1976). L GL SMITH et al., "Oligonucleotide Labeling Methods 4 Difrect Labeling Reagents with a GМ ĸ Novel, Non-Nucleosidic, Chirally Defined 2-Deoxy-β-D-Ribosyl Backbone," Nucleosides & Nucleotides, 15(10):1581-1594 (1996). STEIN et al., "Oligodeoxynucleotides as Inhibitors of Gene Expression: A Review," GN P Cancer Res., 48:2659-2668 (1988). TAKAKURA et al., "Drug Delivery Systems for Macromolecular Drugs," Yakugaku GO Zasshi, 116(7):519-532 (1996), Abstract Only. TOWNSEND, et al., "Binding of N-Linked Bovine Fetuin Glycopeptides to Isolated Rabbit Hepatocytes Gal/GalNAc Hepatic Lectin Discrimination between Galβ(1,4)GlcNAc and Galβ(1,3)GlcNAc in a Triantennary Structure," Biochem., 25: 5716-5725 (1986). TRERÉ et al.. "The Asialoglycoprotein Receptor in Human Hepatocellular Carcinomas: Its Expression on Proliferating Cells," British J. Cancer, 81(3): 404-408 (1999). GR ULBRICH et al., "Synthesis of Biodegradable Polymers for Controlled Drug Release," Annals New York Acad. Sci., 831: 47-56 (1997). VAN BERKEL et al., "The Effect of a Water-Soluble Tris-Galactoside-Terminated GŚ Cholesterol Dervative on the Fate of Low Density Lipoproteins and Liposomes." J.Biol. Chem., 260(5): 2694-2699 (1985). WADHWA et al., "Targeted Gene Delivery with a Low Molecular Weight Glycopeptide Carrier," Bioconjugate Chem., 6: 283-291 (1995). GÜ WADHWA et al., "Receptor Mediated Glycotargeting," J. Drug Targeting, 3: 111-127 WALDNER et al., "Hydrophobic Effects in Duplexes with Modified Oligonucleotide Backbones and RNA," Bioorganic & Medicinal Chemistry Letters, 6(19): 2363-2366 (1996)WEIGEL et al., "Preparation of 6-Aminohexyl D-Aldopyranosides," Carbohydrate Res., 70: 83-91 (1979). WOLFRUM et al., "Fatty acids and Hypolipidemic Drugs Rgulate Peroxisome GXProliferator-activated Receptors Alpha- and Gamma-mediated Gene Expression Via Liver Fatty Acid Binding Protein: A signaling Path to the Nucleus," Proc. Natl. Acad. Sci. USA, 98(5): 2323-2328 (Feb. 2001). WONG et al., "Synthesis of D-galactosamine Derivatives and Binding Studies Using GY Isolated Rat Hepatocytes," Carbohydrate Res. 170: 27-46 (1987). WU et al., "Targeted Delivery and Expression of Foreign Genes in Hepatocytes." GΖ Targeted Diagnosis & Therapy, 4: 127-149 (1991). ZAIA et al., "Inhibition of Human Immunodeficiency Virus by Using an Oligonucleoside HΑ Methylphosphonate Targeted to the tat-3 Gene," J. Virol., 62(10): 3914-3917 (1988).

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